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US-A- 4 164 320
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Description

This invention relates to containers, especially evacuated blood collection tubes.

With the increased emphasis on the use of plastic medical products, a special need exists for improving the barrier properties of articles made of polymers.

Such medical products that would derive a considerable benefit from improving their barrier properties include, but are not limited to, collection tubes and particularly those used for blood collection.

Blood collection tubes require certain performance standards to be acceptable for use in medical applications. Such performance standards include the ability to maintain greater than about 90% original draw volume over a one year period, to be radiation sterilizable and to be noninterfering in tests and analysis.

A critical performance standard of the blood collection tube is the draw volume retention. Draw volume retention depends on the existence of a partial vacuum, or reduced pressure, inside the tube. The draw volume changes in direct proportion to the change in vacuum (reduced pressure). Therefore, draw volume retention is dependent on good vacuum retention.

For example, it is important to maintain the vacuum over a period of time in order to provide appropriate storage life for those tubes prior to their being used. That is, it is important for the vacuum level to be maintained for a period of time prior to the time when a technician or a nurse uses the tube for collecting a blood sample.

Radiation sterilizable means that after the tube is exposed to certain levels of radiation in the sterilization process, there is substantially no change in optical or mechanical and functional properties.

Noninterference in performance of a tube's specifications means that the materials of the tube, such as glass or plastic materials do not interfere with testing and analysis that is typically performed on blood in the tube. Such tests include but are not limited to, hematology, blood chemistry, blood typing, toxicology analysis and therapeutic drug monitoring. Furthermore, the tube must be capable of being subjected to automated machinery such as centrifuges.

US-A-4 809 876 describes a container for foods and beverages formed from a plastic resin and coated with a thin film of diamond-like carbon. The diamond-like carbon film is applied either directly to an interior surface portion or to an exterior surface portion of the container. The diamond-like carbon film reduces gas and vapor permeability of the container and may be formed by radio-frequency discharge, direct or dual ion beam deposition or sputtering. However, the containers of US-A-4 809 876 are not suitable for use in the medical field.

It is the object of the present invention to provide a sample collecting container assembly suitable for use in the medical field.

This object is solved, according to the invention, with the features of the characterising part of claim 1.

With the present invention there is provided a plastic container coated with a barrier label disposed over an outer surface of the plastic container. The barrier label improves the barrier properties of the plastic container, but does not obscure the contents of the plastic container and extends the shelf-life of plastic containers, especially plastic evacuated blood collection devices. The barrier label comprises a diamond composition. The diamond composition may be applied either to an interior surface portion or to an exterior surface portion of the label.

The barrier label may be placed or formed around the container and then adhered to the container by methods such as, but not limited to, an adhesive layer, heating the barrier label and container to a temperature sufficient to cause the barrier label to heat-shrink onto the container or by expanding the container into the barrier label by blow molding.

The diamond composition may provide a transparent, translucent or colorless appearance and may have printed matter applied thereon.

Plastic tubes with barrier labels coated with the diamond composition are able to maintain far better vacuum retention and draw volume retention than previous tubes comprised of polymer compositions and blends thereof without a barrier label. In addition, the labeled tube's water barrier properties would be significantly improved since diamond coatings are substantially nonpolar. Notably is the clarity of the diamond composition, its durability to substantially withstand resistance to impact, abrasion and scratches.

Suitable films to be coated for use as barrier labels according to the present invention include, but are not limited to polypropylene films, low and high density polyethylene films and polyvinylchloride films.

Printing may be placed on the barrier label which is to be used on the container of interest. For example, a product identification, bar code, brand name, company logo, lot number, expiration date and other data and information may all be included on the label surface. Moreover, a matte finish or a corona discharged surface may be developed on the outer surface of the barrier composition so as to make the surface appropriate for writing additional information on the label. Furthermore, another pressure sensitive adhesive label may be placed over the outer surface of the barrier label so as to accommodate various hospital over-labels, for example.

In the drawings:

FIG. 1 is a perspective view of a typical blood collection tube with a stopper.

FIG. 2 is a longitudinal sectional view of the tube of FIG. 1 taken along line 2-2.

FIG. 3 is a longitudinal sectional view of a tube-shaped container similar to the tube of FIG. 1 without a stopper.

FIG. 4 is a longitudinal sectional view of a tube-shaped container similar to the tube of FIG. 1 with a stopper.

Referring to the drawings in which like reference characters refer to like parts throughout the several views thereof, FIGS. 1 and 2 show a typical blood collection tube **10**, having an open end **16**, a closed end **18** and stopper **14** which includes a lower annular portion or skirt **15** which extends into and presses against the inside walls **12** of the tube for maintaining stopper **14** in place. FIG. 2 schematically illustrates that there are three mechanisms for a change in vacuum in a blood collection tube: (A) gas permeation through the stopper material; (B) gas permeation through the tube material and (C) leak at the closure-tube interface. Therefore, when there is substantially no gas permeation and no leak, there is good vacuum retention and good draw volume retention.

FIG. 3 shows the preferred embodiment of the invention, a plastic tube covered by a diamond coated barrier label. The preferred embodiment includes many components which are substantially identical to the components of FIGS. 1 and 2. Accordingly, similar components performing similar functions will be numbered identically to those components of FIGS. 1 and 2, except that a suffix "a" will be used to identify those components in FIG. 3.

Referring now to FIG. 3, the preferred embodiment of the invention, collection tube assembly **20** comprises a plastic tube **10a**, having an open end **16a** and a closed end **18a**. A coating comprising a diamond coated barrier label **25** extends over a substantial portion of the length of the tube which is upon the outer surface of the tube with the exception of open end **16a** and closed end **18a** thereof.

FIG. 4 illustrates an alternate embodiment of the invention, wherein collection tube assembly **40** comprises stopper **48** in place for closing open end **41** of tube **42**. As can be seen, stopper **48** includes an annular upper portion **50** which extends over the top edge of tube **42**. Stopper **48** includes a lower annular portion or skirt **49** which extends into and presses against the inside walls of tube **42** for maintaining stopper **48** in place and also, defines a well **52** which, in turn, defines a septum portion **53** for receiving a cannula therethrough. Thus, the user, once receiving a container such as that shown in FIG. 4 with a sample contained therein, may insert a cannula through septum **53** for receiving part or all of the contents in tube **42** to perform various tests on a sample.

Covering a substantial portion of the length of the tube is a diamond coated barrier label **45**. The barrier label **45** covers substantially most of the tube with the exception of open end **41** thereof. FIG. 4 differs from the embodiment in FIG. 3 in that the tube may be evacuated with the simultaneous placement of stopper **48** therein after the application of a diamond coated barrier label **45** thereover the tube. Alternatively, the diamond coating or diamond coated barrier label may be applied to the tube before it has been evacuated.

An alternate embodiment of the invention also includes a label incorporating both the upper portion of the stopper, as well as the entire container tube. Such an embodiment may be utilized, for example, for sealing the container with the stopper in place. Once a sample has been placed in the tube, the sample cannot be tampered with by removal of the stopper. Additionally, serrations could be included at the tube, stopper interface. The serrations may be registered so that it can be determined if the sealed container has been tampered with.

It will be understood by practitioners-in-the-art, such tubes may contain reagents in the form of additives or coatings on the inner wall of the tube.

A coating comprising a diamond composition forms a clear or translucent barrier. Therefore, the contents of a plastic tube coated with a coating comprising a diamond composition are visable to the observer at the same time identifying information may be displayed over the diamond film after it is applied to the plastic tube.

A coating comprising a diamond composition may be formed on a substrate by radio frequency discharge, direct or dual ion beam deposition, sputtering or plasma chemical vapor deposition, as described in US-A-4,698,256, US-A-4,809,876, US-A-4,992,298 and US-A-5,005,318, the disclosures of which are herein incorporated by reference.

The coating of the present invention is a diamond composition comprising carbon having a major proportion of sp^3 tetrahedral bonding and a minor proportion of sp^2 bonds. In general, the diamond compositions of the present invention may consist of carbon atoms bonded in a dense chemical structure similar to that in a diamond, but without a long range crystal order.

Desirably, the diamond coating is applied to a barrier film by a dual ion beam ballistic alloy process.

A plastic blood collection tube covered with a diamond coated barrier label may effectively be used in such applications as routine chemical analysis, biological inertness, hematology, blood chemistry, blood typing, toxicology analysis or therapeutic drug monitoring and other clinical tests involving body fluids.

If the inner surface of the plastic blood collection tube is also covered by a barrier label, the diamond coating may be hemorepellent and/or have characteristics of a clot activator.

It will be understood that it makes no difference whether the plastic composite container is evacuated or not evacuated in accordance with this invention. The presence of a barrier label on the outer surface of the container has the effect of maintaining the general integrity of the container holding a sample so that it may be properly disposed of without any contamination to

the user. Notably is the clarity of the barrier label and their abrasion and scratch resistance.

The diamond coatings or blends thereof used in accordance with this disclosure, may contain conventional additives and ingredients which do not adversely affect the properties of articles made therefrom.

The barrier label is a polymer film coated with a diamond composition. Suitable film materials include polymeric substrate resins. Polymeric substrate resins include, but are not limited to polyamide, polyolefin and polyester. Polyamide includes but is not limited to, biaxial oriented nylon, aromatic amorphous polyamide, polyvinyl chloride and mixtures thereof. Polyolefin includes, but is not limited to biaxial oriented polypropylene, low density polyethylene, polychlorotrifluoroethylene and mixtures thereof. Polyester includes, but is not limited to, polyethylene terephthalate, polyethylene naphthalate, polyethylene isophthalate and mixtures thereof.

Claims

1. A sample collecting container assembly comprising a plastic container (10a) having an open end (16a), a closed end (18a), an inner surface (12a) and an outer surface, and a layer comprising a diamond-based composition, characterised by a barrier label (25) comprising a polymer film coated with the layer comprising the diamond-based composition, the barrier label (25) being mounted on the outer surface of said plastic container (10a) and extending over a major portion of said outer surface of said plastic container (10a).

2. The assembly of claim 1, wherein said polymer film of said barrier label (25) comprises material selected from the group consisting of polyamide, polyolefin and polyester.

3. The assembly of claim 1 or 2, wherein said layer comprising the diamond-based composition is deposited by radio-frequency discharge, dual ion beam deposition, direct ion beam deposition, sputtering or plasma chemical deposition.

4. The assembly of one of claims 1-3 wherein said barrier label (25) incorporates both, the upper portion of a stopper (48) within the open end (16a) of the plastic container (10a) as well as the entire plastic container (10a).

Patentansprüche

1. Probensammelbehälteranordnung mit einem Kunststoffbehälter (10a), der ein offenes Ende (16a), ein geschlossenes Ende (18a), eine Innenfläche (12a) und eine Außenfläche aufweist, und mit einer Schicht mit einer Zusammensetzung auf Diamantbasis, gekennzeichnet durch ein Sperr-Etikett (25), das eine mit der die Zusammensetzung auf Diamantbasis aufweisenden Schicht beschichtete Polymerfolie aufweist, wobei das Sperr-Etikett (25) auf der Außenfläche des Kunststoffbehälters (10a) angebracht ist und sich über einen Großteil der Außenfläche des Kunststoffbehälters (10a) erstreckt.

2. Anordnung nach Anspruch 1, bei der die Polymerfolie des Sperr-Etiketts (25) Material aufweist, das aus der aus Polyamid, Polyolefin und Polyester bestehenden Gruppe gewählt ist.

3. Anordnung nach Anspruch 1 oder 2, bei der die die Zusammensetzung auf Diamantbasis aufweisende Schicht durch Hochfrequenzentladung, Zwitterionenstrahlbeschichtung, Direktionenstrahlbeschichtung, Sputtern oder plasmachemisches Sputtern aufgebracht wird.

4. Anordnung nach einem der Ansprüche 1 bis 3, bei der das Sperr-Etikett (25) sowohl den oberen Teil eines Stopfens (48) in dem offenen Ende (16a) des Kunststoffbehälters (10a) als auch den gesamten Kunststoffbehälter (10a) erfaßt.

Revendications

1. Un ensemble à récipient pour recueillir un échantillon comprenant un récipient en matière plastique (10a) muni d'une extrémité ouverte (16a), d'une extrémité fermée (18a), d'une surface intérieure (12a) et d'une surface extérieure, et une couche comprenant une composition à base de diamant, caractérisé par une étiquette (25) formant barrière comprenant un film de polymère revêtu avec la couche comprenant la composition à base de diamant, l'étiquette (25) formant barrière étant disposée sur la surface extérieure dudit récipient en matière plastique (10a) et s'étendant sur une partie majeure de ladite surface extérieure dudit récipient en matière plastique (10a).

2. L'ensemble selon la revendication 1, dans lequel ledit film de polymère de ladite étiquette (25) formant barrière comprend un matériau choisi parmi le groupe constitué par le polyamide, les polyoléfines et le polyester.

3. L'ensemble selon la revendication 1 ou 2, dans lequel ladite couche comprenant la composition à base de diamant est déposée par décharge à fréquence radioélectrique, dépôt par faisceau ionique double, dépôt par faisceau ionique direct, pulvérisation ou dépôt chimique au plasma.

4. L'ensemble selon l'une des revendications 1 à 3, dans lequel ladite étiquette (25) formant barrière englobe, à la fois, la partie supérieure d'un bouchon (48) dans l'extrémité ouverte (16a) du récipient en

matière plastique (10a), ainsi que tout le récipient en matière plastique (10a).

FIG-1

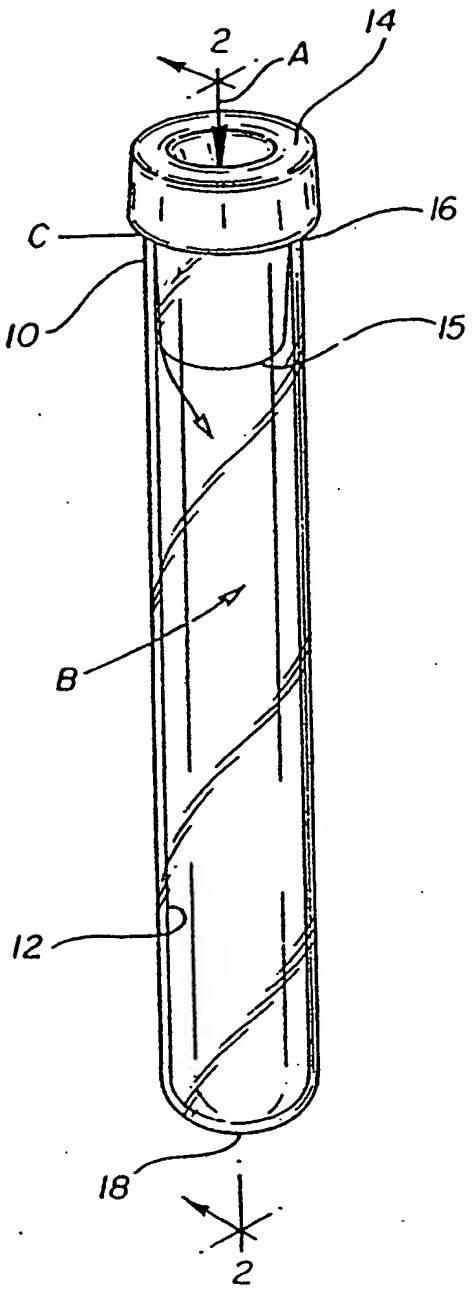

FIG-2

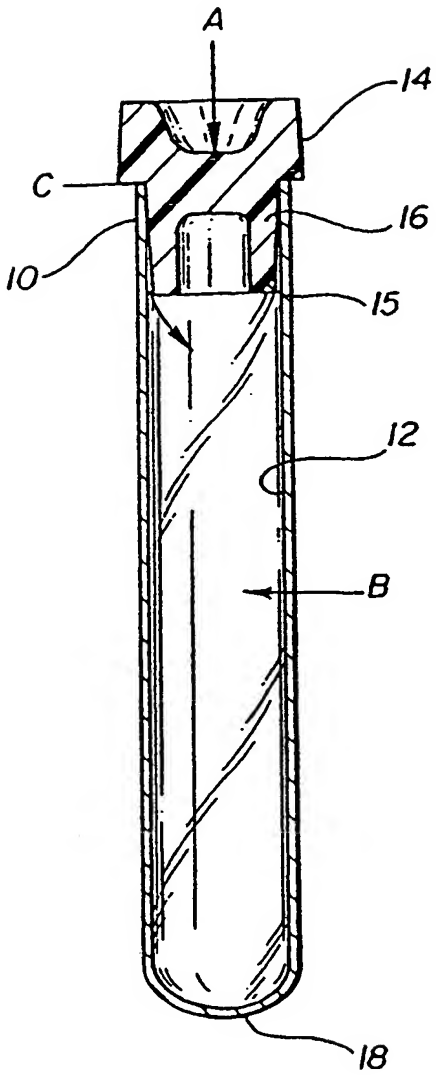

FIG-3

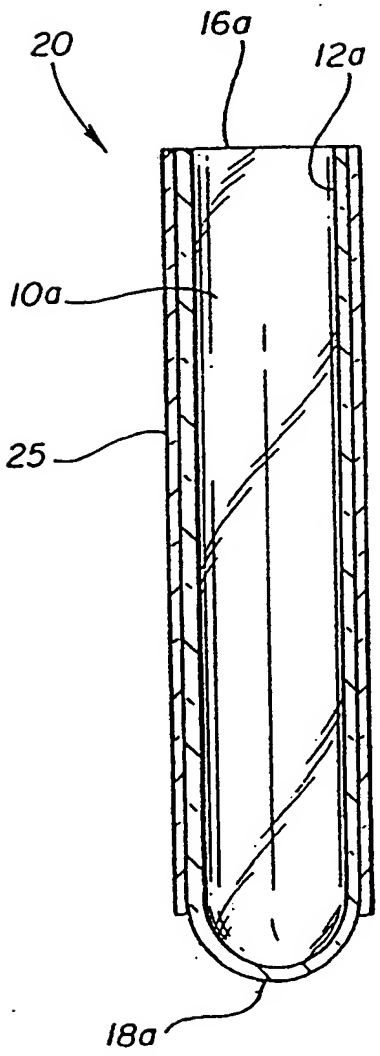

FIG-4